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APPLICATION NO	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/915,726	07/26/2001	Hyeook Kim	3087.00005	6900

7590 12/02/2002

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[REDACTED] EXAMINER

SNEDDEN, SHFRIDAN

ART UNIT	PAPER NUMBER
1653	[REDACTED]

DATE MAILED: 12/02/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/915,776	KIM ET AL.
	Examiner	Art Unit
	Sheridan K Snedden	1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) Responsive to communication(s) filed on 10 September 2002.
- 2a) This action is **FINAL**.                                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) 4-9, 14 and 17-33 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-3, 10-13, 15 and 16 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 26 July 2001 is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) All    b) Some \*    c) None of:
  1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____
2) <input checked="" type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>4</u>	6) <input type="checkbox"/> Other: _____

### **DETAILED ACTION**

1. Applicant's election of invention I, claims 1-3, 10-13 and 15-16 as the claims are related to cytochrome c is acknowledged. Claims 4-9, 14 and 17-33 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **with** traverse in Paper No. 5, filed 30 September 2002. However, as the applicant has not provided any arguments for traversal and thus the elections will be treated as an election without traverse. Claims 1-3, 10-13 and 15-16 are under consideration.

#### ***Drawings***

2. The drawings are objected to for the reasons indicated on the accompanying form PTO 948. Corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance. See 37 CFR 1.85(a) and MPEP 608.02(b).

#### ***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-3, 10-13 and 15-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 and dependent claims thereto is indefinite as it is not clear what the assessment is supposed to show. See also claim 15.

Claim 3 is indefinite because a Markush group must be closed. The "consisting essentially of" in this claim is not closed language. See "consisting of" instead. Additionally, claim 3 recites non-elected subject matter and is therefore indefinite.

Claim 10 provides for the use of a kit, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced. Additionally, the claim recites a kit but fails to recite a structure or composition for the kit that would render the claim definite.

Claims 2-3, 11-13 and 16 are indefinite as they depend from the above claims and do not clarify the ambiguity.

#### ***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Czech *et al.* (J Invest Dermatol. 1997 Jan;108(1):108-12). Czech *et al.* teach a method of measuring actin polymerization upon stimulation of 5-oxo-eicosanoids, which stimulate the production of oxygen metabolites (see Abstract and Methods), which meets to limitation of claim 1, *i.e.*, measuring

polymerization of proteins. Thus, the reference anticipates the claimed invention as it teaches a method of measuring polymerization of proteins to assess oxidative stress.

6. Claims 1-2, 10-13 and 15-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Gadelha *et al.* (J Invest Dermatol. 1997 Jan;108(1):108-12). Gadelha *et al.* teach peroxynitrite anion, a potent oxidant, causes mitochondrial structural and functional alterations through lipid and protein sulphydryl oxidation. Measuring the production of protein aggregates due to membrane thiol cross-linking assessed the oxidative damage cause by the peroxynitrite anion (regarding claim 1 of the instant application). As nitration of proteins results from the reaction with peroxynitrite, the proteins measured are inherently nitrated (regarding claim 2). Regarding claim 15, Gadelha *et al.* demonstrate the protective effect of DTT on protein polymerization that suggests the involvement of disulfide bonds (see Abstract). As such, the formation of disulfide polymerized proteins was measure by Gadelha *et al.* (see Fig. 5). As nitration of proteins results from the reaction with peroxynitrite, the proteins measured are inherently nitrated (regarding claim 16). Gadelha *et al.* teaches an assay for detecting nitrated, polymerized proteins and nitrated, disulfide bonded, polymerized proteins as discussed above, and thus teaches the respective kit for use in assessing oxidant stress (regarding claims 10-13). Thus, the reference anticipates the claimed invention.

*Advisory Information*

7. No claims are allowed.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheridan K Snedden whose telephone number is (703) 305-4843. The examiner can normally be reached on Monday - Friday, 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (703) 308-2923. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 746-3975 for regular communications and (703) 746-3975 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

SKS  
November 27, 2002

*SKS*

*Chris Low*  
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